Amgen Announces Top-Line Results From Phase 3 Study Of ABP 710, Biosimilar Candidate To Infliximab

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Study Evaluated Efficacy and Safety of ABP 710 Compared With Infliximab in Patients With Moderate-to-Severe Rheumatoid Arthritis

Amgen to Seek Regulatory Approvals

THOUSAND OAKS, Calif., June 27, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced results from a Phase 3 study evaluating the efficacy and safety of biosimilar candidate ABP 710 compared with REMICADE® (infliximab) in patients with moderate-to-severe rheumatoid arthritis. The results confirm non-inferiority compared to infliximab but could not rule out superiority based on its primary efficacy endpoint, which compared the response difference measured by 20 percent or greater improvement defined by the American College of Rheumatology (ACR) Criteria, ACR20, at week 22. Key secondary endpoints included ACR50, ACR70 and Disease Activity Score 28-joint count C reactive protein (DAS28-CRP).

The primary endpoint of ACR20 had a prespecified equivalence margin of +/- 15 percent, and the observed upper end of the confidence interval was 15.96 percent. ACR50 and ACR70 trended in the same direction as ACR20. Notably, the DAS28-CRP difference in mean change from baseline was close to zero (-0.01 [-0.20, 0.17]). Overall, the safety profile and immunogenicity were comparable between ABP 710 and infliximab.

"We believe this study confirms no clinically meaningful differences between ABP 710 and infliximab," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Biosimilars are approved based on the analytical, nonclinical and clinical data, and we believe that the totality of the evidence we've generated supports ABP 710 as highly similar to the reference product."

ABP 710 is being developed as a biosimilar to infliximab, an anti-tumor necrosis factor alpha (anti-TNF) monoclonal antibody, which is approved in many regions for the treatment of moderate-to-severe rheumatoid arthritis, chronic severe plaque psoriasis, moderate-to-severe Crohn's disease, moderate-to-severe ulcerative colitis, psoriatic arthritis and ankylosing spondylitis.

Amgen has a total of 10 biosimilars in its portfolio, including two that are approved in the United States (U.S.) and three that are approved in the European Union (EU).

About the Study Design

The above referenced Phase 3 study was a randomized, double-blind trial (study number NCT02937701) that evaluated the efficacy and safety of ABP 710 compared to infliximab in patients with moderate-to-severe rheumatoid arthritis. There were 558 patients enrolled and randomized (1:1) to receive either ABP 710 or infliximab at a dose of 3 mg/kg administered as an infusion on day 1, at weeks 2 and 6, and every 8 weeks thereafter. Among them, 279 patients were randomized to the ABP 710 group and 279 patients were randomized to the infliximab group. The primary endpoint was assessment of ACR20 at week 22. Key secondary endpoints included ACR50, ACR70 and the DAS28-CRP.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory disease of unknown etiology that affects approximately one percent of the adult population worldwide.[1] RA can cause pain, stiffness, swelling and limitations in the motion and function of multiple joints.[2] In RA, joint damage can significantly worsen over time, especially if left untreated and may impair function.[3]

About ABP 710

ABP 710 is being developed as a biosimilar candidate for infliximab, an anti-tumor necrosis factor alpha (anti-TNF) monoclonal antibody, which is approved in U.S., EU and other regions for the treatment of conditions including moderate-to-severe rheumatoid arthritis, chronic severe plaque psoriasis, moderate-to-severe Crohn's disease, moderate-to-severe ulcerative colitis, psoriatic arthritis and ankylosing spondylitis. The active ingredient of ABP 710 is an anti-TNF monoclonal antibody that has the same amino acid sequence as infliximab. ABP 710 has the same pharmaceutical dosage form and strength as infliximab.

About Amgen Biosimilars

Amgen Biosimilars is committed to building upon Amgen's experience in the development and manufacturing of innovative human therapeutics to expand Amgen's reach to patients with serious illnesses. Biosimilars will help to maintain Amgen's commitment to connect patients with vital medicines, and Amgen is well positioned to leverage its four decades of experience in biotechnology to create high-quality biosimilars and reliably supply them to patients worldwide.

For more information, visit www.amgenbiosimilars.com and follow us on www.twitter.com/amgenbiosim.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Forward Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins,

capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key manufacturing facilities and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

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3. Arthritis Foundation. Joint deformities in rheumatoid arthritis. http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/articles/ra-deformities.php. Accessed June 6, 2018.

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